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EXAMINER	
YOUNG, MICAH PAUL	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DAVID W. WYNN, GERARD MCNALLY and NICK PARIKH

Appeal 2010-011409
Application 10/697,546
Technology Center 1600

Before ERIC GRIMES, LORA M. GREEN, and STEPHEN WALSH, *Administrative Patent Judges*.

WALSH, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

This is an appeal under 35 U.S.C. § 134(a) involving claims to a controlled release liquid suspension dosage form comprising first and second portions of particles containing an NSAID. The Patent Examiner rejected

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

Claims 13-16, 18-22, 25-27, 29-31, 34, and 36-46 are on appeal. Claim 26 is representative and reads as follows:

26. A liquid suspension dosage form comprising:

a) a first portion of particles containing an NSAID, said NSAID being released from the dosage form in a substantially immediate manner upon contact of the dosage form with a dissolution medium;

b) a second portion of particles containing said NSAID, said NSAID being released from the particles in a controlled manner upon contact of the dosage form with the dissolution medium; and

c) water, or mixtures of water and a pharmaceutically acceptable water miscible co-solvent selected from the group consisting of glycols, alcohols, and glycerol,

wherein said particles in said second portion are comprised of a core that is substantially covered by a coating thereon, and said coating is comprised of a controlled release composition comprising one or more enteric polymers and one or more insoluble film forming polymers wherein the weight ratio of the insoluble film forming polymer(s) and the enteric polymer(s) is from about 80:20 to about 99: 1, said first portion of particles and said second portion of particles are suspended in component c), wherein the pKa of said NSAID is greater than the pH of the liquid suspension pharmaceutical dosage form, and wherein the dosage form has a duration of therapeutic effect for at least about 12 hours after administration.

OBVIOUSNESS

The Issue

The Examiner's position is that Shah taught a dosage form comprising an immediate release portion comprising uncoated drug particles and an extended release portion comprising coated drug particles. (Ans. 4.) The

Examiner found that Shah disclosed that the extended release portion comprised coated core particles where the coating may comprise a combination of multiple polymer types and copolymers, including enteric polymers and water insoluble film-forming polymers. (*Id.*) Additionally, the Examiner found that Shah disclosed that its formulation may comprise an active ingredient such as an NSAID and may be dispersed into water to form a suspension. (*Id.*)

Although the Examiner found that Shah was silent as to the ratio of the water insoluble polymer relative to the enteric polymers, the Examiner reasoned that the claimed ratio was well within the skill in the art as evidenced by Sakamoto. (*Id.*) Specifically, the Examiner found that Sakamoto disclosed an exemplary controlled release formulation having a coating comprising a combination of water-insoluble polymers and enteric polymers in a ratio of 8.7:1, which the Examiner found to be within the limits of the instant claims. (*Id.* at 5.)

Regarding the pKa of the active agent, the Examiner found that the prior art inherently met this limitation. (*Id.* at 6.) According to the Examiner, "the pKa is a function of the structure of the claimed invention, and is due to the arrangement of the immediate and sustained release particles." (*Id.*) The Examiner reasoned that "[s]ince the prior art disclosed the same arrangement of particles and components, the prior art must also possess the same pKa and pH limitations as the instant claims." (*Id.*) The Examiner found that when the prior art ibuprofen having a pH of 4.4 is suspended in water having a pH of 7, the claim limitation is met because "the NSAID is more acidic than the surrounding suspension." (*Id.*)

According to the Examiner, it would have been obvious to a skilled artisan at the time of the invention to combine the prior art to provide a stable liquid suspension and to prepare the composition of Shah with the ratio of polymers disclosed in Sakamoto to deliver a stable drug release over an extended period of time to treat pain. (*Id.*)

Appellants contend that the claimed invention would not have been obvious over the combined references. (App. Br. 8.) Appellants assert that Shah "teaches away from the use of enteric polymers" at all in the coating of its tablets. (*Id.* at 6.) Additionally, Appellants contend that the Examiner did not address how the combined references would have suggested to a skilled artisan "to maintain the pH of a liquid suspension below the pKa of the NSAID (e.g., maintaining the suspension below a pH of 4.4 for particles containing ibuprofen)." (*Id.* at 7.)

The dispositive issue with respect to the rejection is whether the Examiner established that combination of Shah and Sakamoto suggested "the pKa of said NSAID is greater than the pH of the liquid suspension pharmaceutical dosage form," as claimed.

Principles of Law

A conclusion that the claimed subject matter is prima facie obvious must be supported by evidence, as shown by some objective teaching in the prior art or by knowledge generally available to one of ordinary skill in the art that would have led that individual to combine the relevant teachings of the references to arrive at the claimed invention. *See In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988).

Analysis

We agree with Appellants that the Examiner has not established that the prior art suggested the claimed dosage form "wherein the pKa of said NSAID is greater than the pH of the liquid suspension pharmaceutical dosage form." The Examiner found the limitation inherently met by the composition of the prior art because the prior art disclosed the same arrangement of particles and components as the claimed invention. According to the Examiner the claim limitation is met because prior art's NSAID is more acidic than its surrounding suspension. (Ans. 6.)

However, the instantly claimed invention does not require the NSAID to be more acidic than the liquid suspension. Rather, the claimed invention requires the pH of the suspension to be more acidic than the pKa of the NSAID. Further, the Examiner has not established that the coating components are responsible for the suspension pH. As the Examiner pointed out, the Specification describes using a buffering agent to have the pKa of the active ingredient to be greater than the pH of the suspension. (*Id.* 9.) The fact that the claims do not recite a buffering agent does not establish that the lower pH of the claimed suspension is an inherent property of the prior art, as Examiner additionally contends. (*Id.*)

Summarizing, the Examiner has not supported the finding that the prior art inherently met the disputed claim limitation with the required evidence. *See Fine*, 837 F.2d at 1074.

CONCLUSION OF LAW

The Examiner has not established that combination of Shah and Sakamoto suggested "the pKa of said NSAID is greater than the pH of the liquid suspension pharmaceutical dosage form," as claimed.

SUMMARY

We reverse the rejection of claims 13-16, 18-22, 25-27, 29-31, 34, and 36-46 under 35 U.S.C. § 103(a) as unpatentable over Shah and Sakamoto.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

REVERSED

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